

**CLE DE PEAU BEAUTE RADIANT FOUNDATION I10- octinoxate and titanium dioxide cream**  
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**CLE DE PEAU BEAUTE RADIANT FOUNDATION O20- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION O30- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION B10- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION B20- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION B30- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION BF20- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION O40- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION O50- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION O60- octinoxate and titanium dioxide cream**  
**CLE DE PEAU BEAUTE RADIANT FOUNDATION WB20- octinoxate and titanium dioxide cream**  
**SHISEIDO AMERICAS CORPORATION**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**CLÉ DE PEAU BEAUTÉ RADIANT FOUNDATION**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
OCTINOXATE 4.4%	Sunscreen
TITANIUM DIOXIDE 1.2%	Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating

- reapply at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

### **Inactive Ingredients**

WATER•DIMETHICONE•DIPHENYLSILOXY PHENYL TRIMETHICONE•DIPROPYLENE GLYCOL•GLYCERIN•BUTYLENE GLYCOL•PEG-10 DIMETHICONE•PEG-20•LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE•SYNTHETIC FLUORPHLOGOPITE•PEG-6•PEG-32•DISTEARDIMONIUM HECTORITE•DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER•TREHALOSE•PEG/PPG-14/7 DIMETHYL ETHER•SODIUM ACETYLATED HYALURONATE•ROSA ROXBURGHII FRUIT EXTRACT•ORIGANUM MAJORANA LEAF EXTRACT•POLYQUATERNIUM-51•HYDROLYZED CONCHIOLIN PROTEIN•HYDROLYZED SILK•DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE•ALUMINA•DIMETHICONE/PHENYL VINYL DIMETHICONE CROSSPOLYMER•SORBITAN SESQUIISOSTEARATE•TRIETHOXYCAPRYLYLSILANE•TRISODIUM EDTA•ALUMINUM DISTEARATE•ALUMINUM HYDROXIDE•POLYSILICONE-2•POLYMETHYLSILSESQUIOXANE•TRIETHOXYSIYLETHYL POLYDIMETHYLSILOXYETHYL DIMETHICONE•HYDROGEN DIMETHICONE•SILICA•VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER•TIN OXIDE•BHT•TOCOPHEROL•THEANINE•SODIUM DEHYDROACETATE•METHYLPARABEN•ETHYLPARABEN•PHENOXYETHANOL•FRAGRANCE•TITANIUM DIOXIDE•IRON OXIDES•MICA•

### **Other information**

- protect this product in this container from excessive heat and direct sun.

### **Questions or comments?**

Call toll free 1-800-906-7503

### **PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - I10**

**clé de peau**  
BEAUTÉ

*radiant cream foundation*

**BROAD SPECTRUM SPF 24**  
**SUNSCREEN**

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - O10**

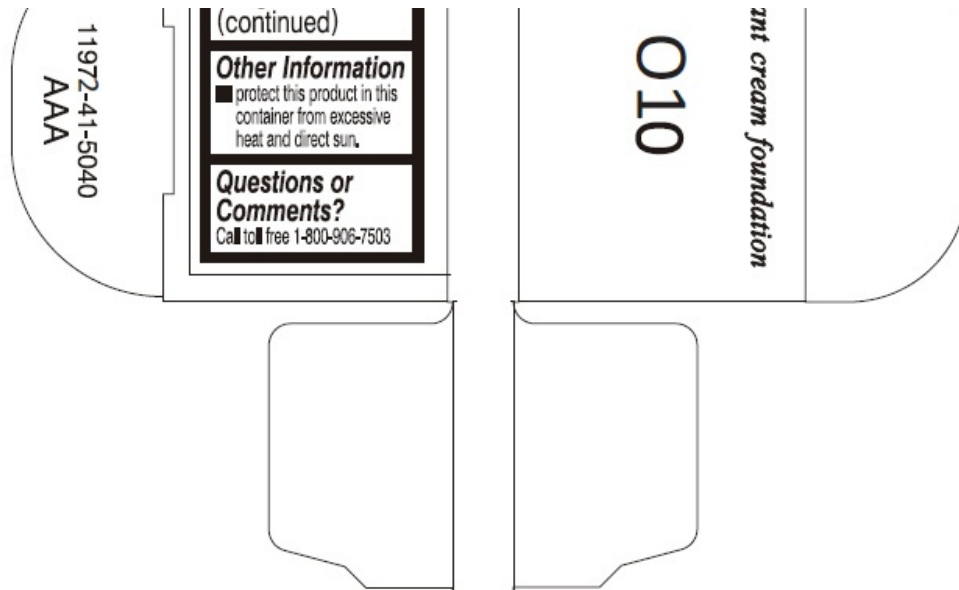
clé de peau  
BEAUTÉ

*radiant cream foundation*

**BROAD SPECTRUM SPF 24  
SUNSCREEN**

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - O20**

**clé de peau  
BEAUTÉ**

***radiant cream foundation***

***BROAD SPECTRUM SPF 24  
SUNSCREEN***

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - O30**

**clé de peau**  
**BEAUTÉ**

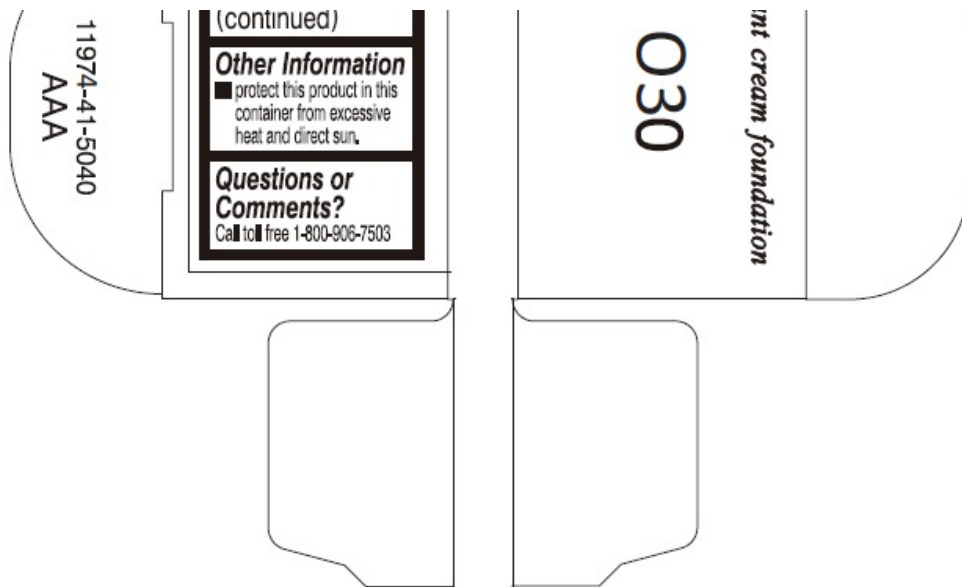
***radiant cream foundation***

***BROAD SPECTRUM SPF 24***  
***SUNSCREEN***

21mL NET WT. .87 OZ.







**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - B10**

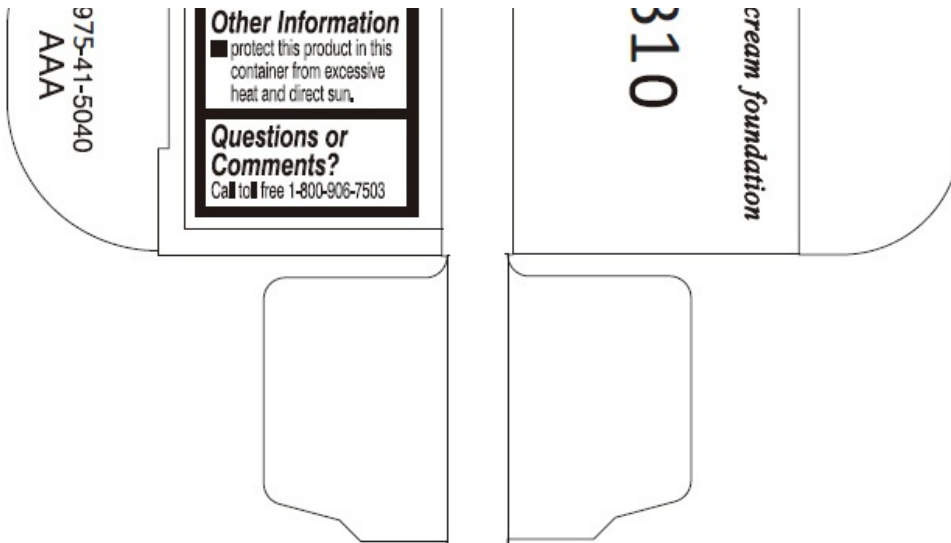
**clé de peau**  
**BEAUTÉ**

***radiant cream foundation***

***BROAD SPECTRUM SPF 24***  
***SUNSCREEN***

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - B20**

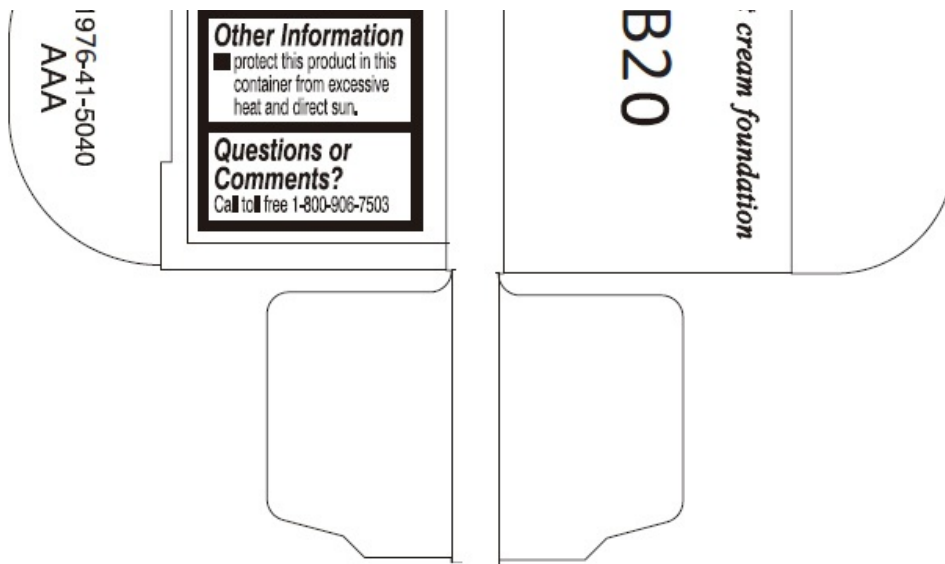
**clé de peau  
BEAUTÉ**

***radiant cream foundation***

***BROAD SPECTRUM SPF 24  
SUNSCREEN***

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - B30**

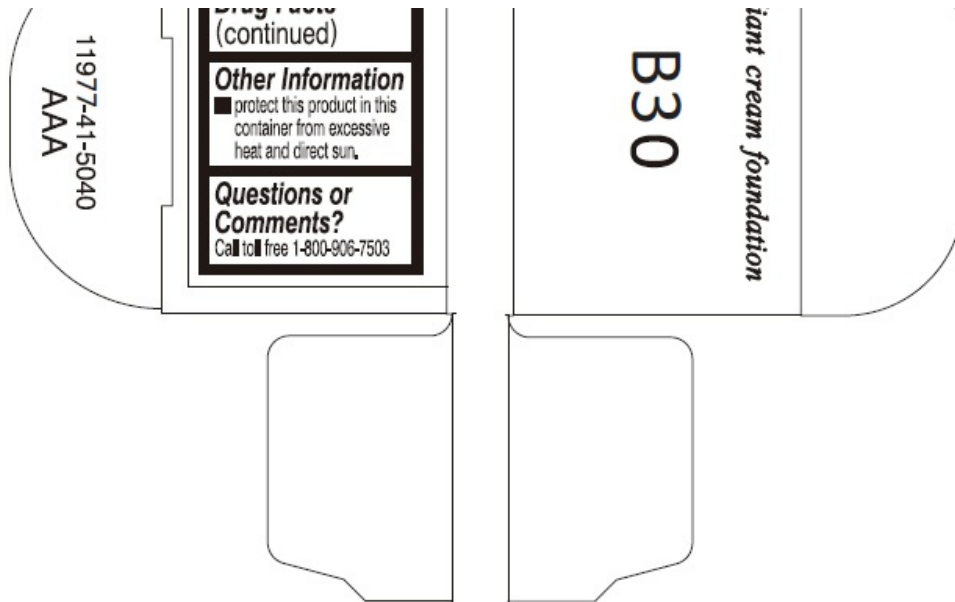
**clé de peau**  
**BEAUTÉ**

*radiant cream foundation*

**BROAD SPECTRUM SPF 24**  
**SUNSCREEN**

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - BF20**

**clé de peau**

**BEAUTÉ**

***radiant cream foundation***

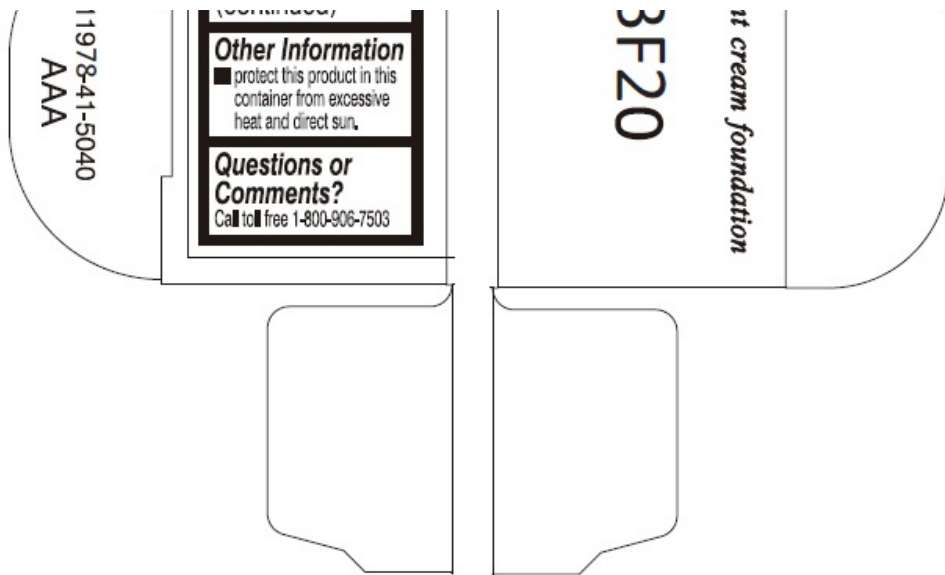
***BROAD SPECTRUM SPF 24***

***SUNSCREEN***

21mL NET WT. .87 OZ.







**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - O40**

**clé de peau**  
**BEAUTÉ**

***radiant cream foundation***

***BROAD SPECTRUM SPF 24***  
***SUNSCREEN***

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - O50**

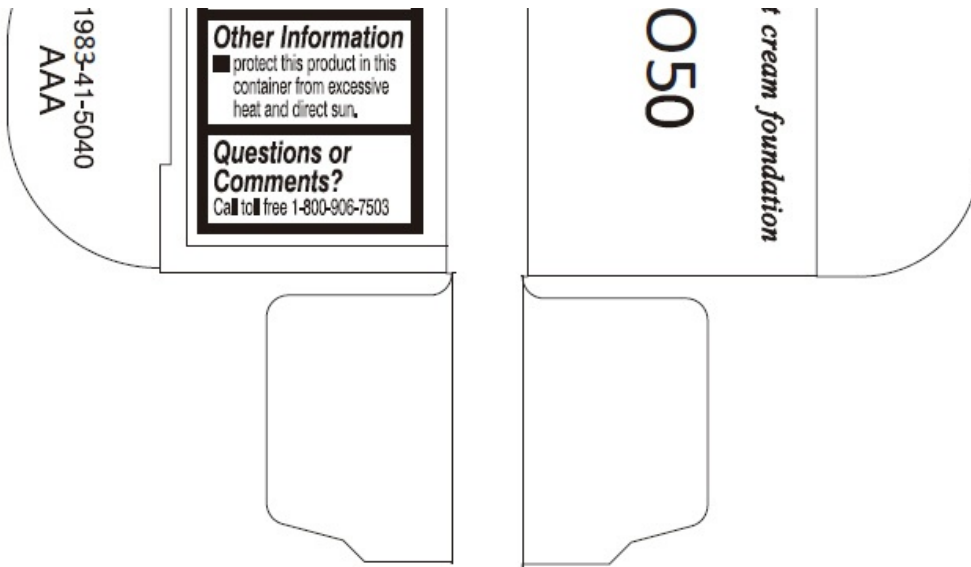
**clé de peau**  
**BEAUTÉ**

***radiant cream foundation***

***BROAD SPECTRUM SPF 24***  
***SUNSCREEN***

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - O60**

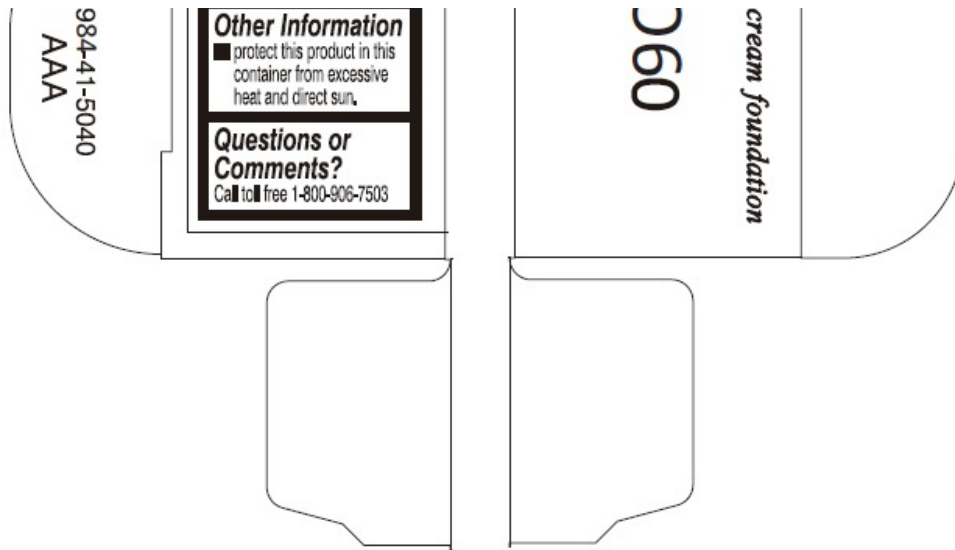
**clé de peau**  
BEAUTÉ

*radiant cream foundation*

**BROAD SPECTRUM SPF 24**  
**SUNSCREEN**

21mL NET WT. .87 OZ.





**PRINCIPAL DISPLAY PANEL - 21 mL Tube Carton - WB20**

**clé de peau**  
**BEAUTÉ**

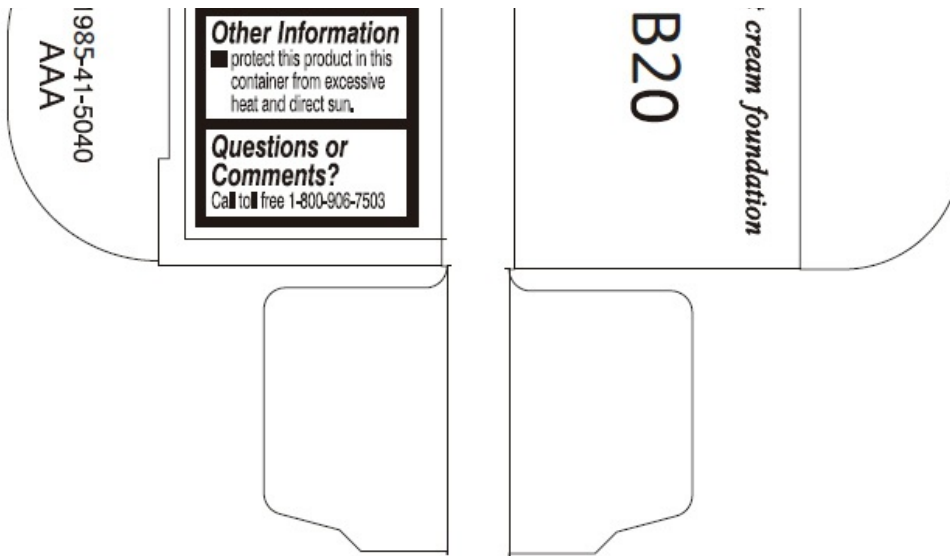
***radiant cream foundation***

***BROAD SPECTRUM SPF 24***  
***SUNSCREEN***

21mL NET WT. .87 OZ.







## CLE DE PEAU BEAUTE RADIANT FOUNDATION I10

octinoxate and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-272
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
TREHALOSE (UNII: B8WCK70T7I)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
ORIGANUM MAJORANA (UNII: R40XM3HU5X)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	

ALUMINUM OXIDE (UNII: LMI26O6933)
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)
EDETATE TRISODIUM (UNII: 420IP921MB)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYLPARABEN (UNII: A2BC7HI9T)
ETHYLPARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492Z3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-272-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION O10

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-273
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

GLYCERIN (UNII: PDC6A3C0OX)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
TREHALOSE (UNII: B8WCK70T7I)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)
ORIGANUM MAJORANA (UNII: R40XM3HU5X)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
ALUMINUM OXIDE (UNII: LMI26O6933)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
EDETATE TRISODIUM (UNII: 420IP921MB)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YO1)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYL PARABEN (UNII: A218C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-273-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION O20

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-274
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<b>Route of Administration</b>	TOPICAL	
<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL
<b>Inactive Ingredients</b>		
<b>Ingredient Name</b>	<b>Strength</b>	
WATER (UNII: 059QF0K00R)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)		
DIPROPYLENE GLYCOL (UNII: E107L85C40)		
GLYCERIN (UNII: PDC6A3C0OX)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)		
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)		
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)		
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)		
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)		
TREHALOSE (UNII: B8WCK70T7I)		
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)		
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)		
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)		
ORIGANUM MAJORANA (UNII: R40XM3HU5X)		
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)		
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)		
EDETATE TRISODIUM (UNII: 420IP921MB)		
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)		
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STANNIC OXIDE (UNII: KM7N50LOS6)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)		
THEANINE (UNII: 8021PR16QO)		
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)		
METHYL PARABEN (UNII: A2I8C7HI9T)		
ETHYL PARABEN (UNII: 14255EXE39)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
FERROSFERRIC OXIDE (UNII: XM0M87F357)		
MICA (UNII: V8A1AW0880)		
<b>Packaging</b>		

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-274-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION O30

octinoxate and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-275
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	292 mg in 21 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0K00R)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
GLYCERIN (UNII: PDC6A3C0OX)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)			
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)			
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)			
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)			
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)			
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)			
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)			
TREHALOSE (UNII: B8WCK70T7I)			
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)			
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)			
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)			
ORIGANUM MAJORANA (UNII: R40XM3HU5X)			
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)			
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)			
EDETATE TRISODIUM (UNII: 420IP921MB)			
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)			
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)			
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)			

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYLPARABEN (UNII: A2B8C7HI9T)
ETHYLPARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-275-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION B10

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-276
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
TREHALOSE (UNII: B8WCK70T7I)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)
ORIGANUM MAJORANA (UNII: R40XM3HU5X)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
ALUMINUM OXIDE (UNII: LMI26O6933)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
EDETATE TRISODIUM (UNII: 420IP921MB)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYL PARABEN (UNII: A2B8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-276-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION B20

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-277
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL



TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)

TITANIUM DIOXIDE

292 mg in 21 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
TREHALOSE (UNII: B8WCK70T7I)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
ORIGANUM MAJORANA (UNII: R40XM3HU5X)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YO1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
THEANINE (UNII: 8021PR16QO)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICA (UNII: V8A1AW0880)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-277-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part352	08/01/2016	
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## CLE DE PEAU BEAUTE RADIANT FOUNDATION B30

octinoxate and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-278
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
TREHALOSE (UNII: B8WCK70T7I)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
ORIGANUM MAJORANA (UNII: R40XM3HU5X)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
THEANINE (UNII: 8021PR16QO)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
FERROSFERRIC OXIDE (UNII: XM0M87F357)				
MICA (UNII: V8A1AW0880)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-278-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	08/01/2016		

<b>CLE DE PEAU BEAUTE RADIANT FOUNDATION BF20</b>				
octinoxate and titanium dioxide cream				
<b>Product Information</b>				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-279	
Route of Administration	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
Ingredient Name	Basis of Strength	Strength		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL		
<b>Inactive Ingredients</b>				
Ingredient Name	Strength			
WATER (UNII: 059QF0K00R)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
GLYCERIN (UNII: PDC6A3C0OX)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)				
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)				
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)				
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)				
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)				
TREHALOSE (UNII: B8WCK70T7I)				
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)				
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)				
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)				
ORIGANUM MAJORANA (UNII: R40XM3HU5X)				
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)				

DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
ALUMINUM OXIDE (UNII: LMI26O6933)
TRIETHOXYCAPRYL SILANE (UNII: LDC331P08E)
EDETATE TRISODIUM (UNII: 420IP921MB)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9U)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YO1)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYL PARABEN (UNII: A2B8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-279-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION O40

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-280
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL

### Inactive Ingredients

Ingredient Name	Strength
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	

DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
TREHALOSE (UNII: B8WCK70T7I)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)
ORIGANUM MAJORANA (UNII: R40XM3HU5X)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
ALUMINUM OXIDE (UNII: LMI26O6933)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
EDETATE TRISODIUM (UNII: 420IP921MB)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YO1)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYL PARABEN (UNII: A2B8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)
WATER (UNII: 059QF0K00R)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
GLYCERIN (UNII: PDC6A3C0OX)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-280-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION O50

octinoxate and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-281
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	WATER (UNII: 059QF0KO0R)		
	DIMETHICONE (UNII: 92RU3N3Y1O)		
	DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)		
	DIPROPYLENE GLYCOL (UNII: E107L85C40)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
	PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)		
	POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)		
	LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)		
	POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)		
	POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)		
	DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)		
	TREHALOSE (UNII: B8WCK70T7I)		
	PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)		
	SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)		
	ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)		
	ORIGANUM MAJORANA (UNII: R40XM3HU5X)		
	POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)		
	DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)		
	ALUMINUM OXIDE (UNII: LM26O6933)		
	TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)		
	EDETATE TRISODIUM (UNII: 420IP921MB)		
	ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)		
	ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
	POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)		
	HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	STANNIC OXIDE (UNII: KM7N50LOS6)		
	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
	.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)		
	THEANINE (UNII: 8021PR16QO)		
	SODIUM DEHYDROACETATE (UNII: 8W46YN971G)		
	METHYL PARABEN (UNII: A2I8C7HI9T)		
	ETHYL PARABEN (UNII: 14255EXE39)		
	PHENOXYETHANOL (UNII: HIE492ZZ3T)		
	FERRIC OXIDE RED (UNII: 1K09F3G675)		
	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
	FERROSFERRIC OXIDE (UNII: XM0M87F357)		
	MICA (UNII: V8A1AW0880)		
<b>Packaging</b>			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-281-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	08/01/2016		

## CLE DE PEAU BEAUTE RADIANT FOUNDATION O60

octinoxate and titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-282
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
GLYCERIN (UNII: PDC6A3C0OX)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)			
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)			
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)			
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)			
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)			
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)			
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)			
TREHALOSE (UNII: B8WCK70T7I)			
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)			
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)			
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)			
ORIGANUM MAJORANA (UNII: R40XM3HU5X)			
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)			
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)			
EDETATE TRISODIUM (UNII: 420IP921MB)			
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)			
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)			
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)			

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYL PARABEN (UNII: A2B8C7H9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-282-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

## CLE DE PEAU BEAUTE RADIANT FOUNDATION WB20

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-283
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1072 mg in 21 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	292 mg in 21 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	



DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
TREHALOSE (UNII: B8WCK70T7I)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)
ORIGANUM MAJORANA (UNII: R40XM3HU5X)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
ALUMINUM OXIDE (UNII: LMI26O6933)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
EDETATE TRISODIUM (UNII: 420IP921MB)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
THEANINE (UNII: 8021PR16QO)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHYL PARABEN (UNII: A2B8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-283-60	1 in 1 CARTON	08/01/2016	
1		21 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2016	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-272, 58411-273, 58411-274, 58411-275, 58411-276, 58411-277, 58411-278, 58411-279, 58411-280, 58411-281, 58411-282, 58411-283) , analysis(58411-272, 58411-273, 58411-274, 58411-275, 58411-276, 58411-277, 58411-278, 58411-279, 58411-280, 58411-281, 58411-282, 58411-283)